

CLAIMS

1. An apparatus suitable for use in investigating multi-phase biological tissue histology, which apparatus comprises a trans-ductally deployable probe mounting a periodically
5 displaceable body of at least one tactile sensing device, said periodically displaceable body having an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N, said displaceable body being
10 provided with a displacement device having a displacement controller for controlling at least said excitation frequency, said displaceable body being coupled to a displacement monitoring device and a displacement force monitoring device, for monitoring the viscoelastic response of said biological
15 tissue to periodic compression by said displacement force applied to said tissue by periodic displacement of said periodically displaceable body.
2. An apparatus according to claim 1 wherein said probe is
20 formed and arranged so as to be trans-ductally deployable in at least one of the genito-urinary tract in males and females, the gastro-intestinal tract, the respiratory tract, and within the arterial and venous vasculature system.
- 25 3. An apparatus according to claim 1 for trans-urethral deployment, wherein said probe has a diameter of not more than 5mm.
4. An apparatus according to claim 3 wherein said probe has a
30 length of from 1 to 3 cms.
5. An apparatus according to any one of claims 1 to 4 wherein said displaceable body is actuated via at least one of: a pressurised fluid circuit, a mechanical drive system, and a
35 piezoelectric actuator.

6. An apparatus according to any one of claims 1 to 5 wherein said probe is mounted at the distal end of an elongate, transductally deployable, deployment device.
- 5 7. An apparatus according to claim 6 wherein said displaceable body is actuated by a proximally mounted motor.
8. An apparatus according to claim 6 wherein said displaceable body is actuated by a distally mounted motor
- 10 drivingly connected to the displaceable body via said elongate deployment device.
9. An apparatus according to any one of claims 1 to 8 wherein said displaceable body comprises at least one micro-piston
- 15 actuated via a pressurised fluid circuit.
10. An apparatus according to any one of claims 1 to 8 wherein said displaceable body comprises at least one shoe mounted on a piezoelectric device sandwiched between said shoe
- 20 and a stress detector element, formed and arranged for monitoring strain therein, thereby to determine the force applied by said displacement body to tissue contacted thereby in use of said apparatus.
- 25 11. An apparatus according to any one of claims 1 to 10 wherein at least one of the area of the force-transmitting surface of the displaceable body, used to apply force to the tissue in use of the apparatus, and the magnitude of the force applied to the displaceable body, is formed and arranged so as
- 30 to be user-adjustable.
12. An apparatus according to any one of claims 1 to 11 wherein said displacement device incorporates an actuator whose position is controlled whereby the control signal for

said actuator may be used to monitor displacement of the displaceable body.

13. An apparatus according to any one of claims 1 to 12
5 wherein a force detector is incorporated in at least one of the displaceable body displacement controller, the force source, and the displaceable body itself.

14. An apparatus according to any one of claims 1 to 13
10 wherein is provided a displacement controller formed and arranged for application of selected ones of a plurality of different excitation frequencies.

15. An apparatus according to any one of claims 1 to 14
15 wherein is provided a displacement controller formed and arranged for controlling each of said excitation frequency and stroke length.

16. An apparatus according to any one of claims 1 to 15,
20 which includes a position control device for changing the position of the displaceable body within a body duct, in use of the apparatus, so as to successively bring it into contact with a plurality of different duct surface portions.

25 17. An apparatus according to any one of claims 1 to 16 which includes a processing unit formed and arranged for processing displacement and displacement force data so as to generate at least one of dynamic modulus and Amplitude Ratio.

30 18. A method for producing a histological profile of a biological tissue adjacent a duct comprising the steps of:
a) providing an apparatus according to claim 1;
b) transductally inserting the probe of said apparatus to bring the periodically displaceable body of said probe into

contact with the ductal surface of said biological tissue at a plurality of positions across said ductal surface;

- c) subjecting said displaceable body to a periodic displacement at an excitation frequency bandwidth of from 1 Hz to 500 kHz, a maximum stroke of less than 1mm and a displacement force in the range of from 0.01 N to 1 N so as to periodically compress said biological tissue at said contact positions across said ductal surface;
- d) monitoring the viscoelastic response of said tissue at each of said surface contact tissue positions to compression by said body; and
- e) generating a profile of the viscoelastic response of the tissue across said ductal surface.

15 19. A method as claimed in claim 18 which includes the preliminary step of determining values of displacement frequency, displacement stroke length and displacement force suitable for histological profiling of the type of biological tissue to be profiled.

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20. A method as claimed in claim 18 or claim 19, wherein said displacement body is contracted with a said plurality of tissue surface contact positions, which plurality is distributed axially and/or circumferentially of said duct.

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21. A method of diagnosing a condition manifested by a histological abnormality in biological tissue adjacent a body duct comprising the steps of:

- a) providing an apparatus according to claim 1;
- 30 b) trans-ductally inserting the probe of said apparatus to bring the periodically displaceable body of said probe into contact with the ductal surface of said biological tissue at successive ones of a plurality of positions across said ductal surface;

- c) subjecting said displaceable body to a periodic displacement at an excitation frequency bandwidth of from 1 Hz to 500 kHz, a maximum stroke length of less than 1mm and a displacement force in the range of from 0.01 N to 1 N so as to
- 5 periodically compress said biological tissue at said contact positions across said ductal surface;
- d) monitoring the viscoelastic response of said tissue at each of said tissue surface contact positions to compression by said body;
- 10 e) generating a profile of the viscoelastic response of the tissue across said ductal surface;
- g) comparing said generated viscoelastic response profile with viscoelastic response profiles of such tissue having known histological characteristics.